03-08-04

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

RICH, Ivan N.

Serial No.:

10/645,077

Filed:

August 21, 2003

For:

HIGH-THROUGHPUT ASSAY OF HEMATOPOIETIC STEM AND

PROGENITOR CELL PROLIFERATION

CERTIFICATE OF EXPRESS MAIL

Mail Stop IDS Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

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Enclosed for filing in the above case are the following documents:

Information Disclosure Statement Form PTO 1449 55 References Return Postcard

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Docket No.:

R103 1031.1

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In re application of:)	
	RICH)	Docket No.: R103 1031.1
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INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents Post Office Box 1450 Alexandria, Virginia 22313

Sir:

Applicant hereby voluntarily discloses the items listed on the attached Form PTO-1449 to the Assistant Commissioner for Patents. Copies of items (L - NNN) are enclosed herewith.

Applicant further reserves the right to establish the patentability of the claimed invention over any of the listed information should they be applied as references, and/or to prove that some of the cited information may not be prior art, and/or to prove that some of the cited information may not be enabling for the teachings they purport to offer. This statement further should not be construed as a representation that an exhaustive search has been made, or that the information cited herewith is material, or that there does not exist information more material to the examination of the present Application. The Examiner is specifically requested not to rely solely on the information submitted herein. On the contrary, the Examiner is requested to conduct an independent and thorough review of the information, and to form independent opinions as to their significance.

It is respectfully requested that the Examiner initial and return copies of the enclosed PTO-1449 and to indicate in the official file wrapper of the above-identified patent application that each item of the cited information has been considered.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to account no. 09-0528.

Date: 3/5/2004

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	M	l l		Circadian Periodicity tology, 12:61-67 (198		ony-Forn	ning	Cells"	; Aardal,	Nils-
	N		"Circadian Variations in Mouse Bone Marrow"; Aardal, N.P. & Laerum, O.D., Experimental Hematology, Vol. 11, No. 9, pp. 792-801 (1983)							
	0	Cell Defect"; Abk	"Cyclic Hematopoiesis in Dogs: Studies of Erythroid Burst-forming Cells Confirm an Early Stem Cell Defect"; Abkowitz, Janis L., Holly, Richard D., Hammond, William P. IV, Experimental Hematology, 16:941-945 (1988)							

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P	"Hematopoietic Effects of Benzene Inhalation Assessed by Long-term Bone Marrow Culture"; Abraham, Nadar G., Environmental Health Perspectives, Vol. 104, Supplement 6, pp. 1277-82 (1996)
Q	"Circadian cell cycle variations of erythro- and myelopoiesis in humans"; Abrahamsen, JF, Smaaland, R, Sothern, RB, Laerum OD, European Journal of Haematology, Vol. 58, pp. 333-45 (1997)
R	"Circadian and seasonal variations of hematopoiesis in cord blood"; Baudoux, E., et al, Bone Marrow Transplantation, Supplement 1, S12, p. 22 (1998)
S	"Toxicity on Human Hemopoietic Progenitors of 2'-2'-Difluoro-2'Deoxycytidine (Gemcitabine)"; Botta, Marco, et al, Anticancer Research, Vol. 18, pp. 1037-42 (1998)
T	"Measurement of the ADP:ATP ratio in human leukaemic cell lines can be used as an indicator of cell viability, necrosis and apoptosis"; Bradbury, D.A., Simmons, T.D., Slater, K.J., Crouch, S.P.M., Journal of Immunological Methods 240, pp. 79-92 (2000)
U	"The Growth Of Mouse Bone Marrow Cells <i>In Vitro</i> "; Bradley, T.R., Metcalf, D, Aust. J. Experimental Biological Medical Science, 44, pp. 287-300 (1966)
V	"Cyclic oscillations of neutrophils, monocytes, and CD8-positive lymphocytes in a healthy subject"; Carulli, Giovanni, et al, Haematologica, Vol. 85(4), pp. 447-48 (2000)
W	"Azidothymidine and interferon-α in vitro effects on hemotopoiesis: Protective in vitro activity of IL-1 and GM-CSF"; Castello, G, et al, Experimental Hematology 23, pp. 1367-71 (1995)
X	"Hematotoxicity of 5-Fluorouracil-Leucovorin in a Setting of Adjuvant Chemotherapy"; Cerruti, Allessandro, et al, Anticancer Research 14, pp. 2163-66 (1994)
Y	"Chemopreventive Agent Resveratrol, a Natural Product Derived From Grapes, Triggers CD95 Signaling-Dependent Apoptosis in Human Tumor Cells"; Clement, M., et al, Blood, Vol. 92, No. 3, pp. 996-1002 (1998)
Z	"Idarubicinol myelotoxicity: a comparison of in vitro data with clinical outcome in patients treated with high-dose idarubicin"; Corsini, C., et al, British Journal of Cancer, 82(3), pp. 524-528 (2000)
AA	"The use of ATP bioluminescence as a measure of cell proliferation and cytotoxicity"; Crouch, S.P.M., et al, Journal of Immunological Methods, 160, pp. 81-88 (1993)
BB	"Experimental basis for increasing the therapeutic index of carboplatin in brain tumor therapy by pretreatment with WR compounds"; Dox, F., et al, Cancer Chemother Pharmacol, 28, pp. 308-310 (1991)
CC	"Benzene-Induced Hematotoxicity and Bone Marrow Compensation in B6C371 Mice"; Farris, Georgia M., et al, Fundamental and Applied Toxicology 36, pp. 119-29 (1997)
DD	"Hematotoxicity on human bone marrow- and unbilical coard blood-derived progenitor cells and in vitro therapeutic index of methoxymorpholinyldoxorubicin and its metabolites"; Ghielmini, M., et al, Cancer Chemother Pharmacol 42, pp. 235-40 (1998)
EE	"In vitro schedule-dependency of myelotoxicity and cytotoxicity of Ecteinascidin 743 (ET-743)"; Ghielmini, M., et al, Annals of Oncology 9, pp. 989-93 (1998)

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VV	"A sensitive sandwich ELISA for measuring erythropoietin in human serum"; Noe, G., et al, British Journal of Haematology, Vol. 80, pp. 285-292 (1992)
ww	"Roles for In Vitro Myelotoxicity Tests in Preclinical Drug Development and Clinical Trial Planning"; Parchment, R.E., et al, Toxicologic Pathology, Vol. 21, No. 2, pp. 241-50 (1993)
XX	"Predicting hematological toxicity (myelosuppression) of cytotoxic drug therapy from <i>in vitro</i> tests"; Parchment, R.E., et al, Ann Oncol., Vol. 9, pp. 357-364 (1998)
YY	"In vitro Study of Pesticide Hematotoxicity in Human and Rat Progenitors"; Parent-Massin, D. & Thouvenot, D., Journal of Pharmacological and Toxicological Methods, Vol. 30, pp. 203-207 (1993)
ZZ	"Use of Limiting-Dilution Type Long-Term Marrow Cultures in Frequency Analysis of Marrow-Repopulating and Spleen Colony-forming Hematopoietic Stem Cells in the Mouse"; Ploemacher, R.E., et al, Blood, Vol. 78, No. 10, pp. 2527-2533 (1991)
AAA	"The Induction of Clones of Normal Mast Cells By A Substance From Conditioned Medium"; Pluznik, D.H. & Sachs, L., Experimental Cell Research, Vol. 43, pp. 553-63 (1966)
BBB	"The Effect of Stem Cell Proliferation Regulators Demonstrated With an in vitro Assay"; Pragnell, I.B., et al, Blood, Vol. 72, No. 1, pp. 196-201 (1988)
CCC	"ECVAM's in-house prevalidation/validation studies in the areas of haematotoxicity, reproductive toxicity, metabolism-mediated toxicity and epithelial barrier function"; Prieto, Pilar, The Sciences of the Total Environment, Vol. 247, pp. 349-354 (2000)
DDD	"The Effect of 5-Fluorouracil on Erythropoiesis"; Rich, Ivan, Blood, Vol. 77, No. 6, pp. 1164-70 (1991)
EEE	"The Developmental Biology of Hemopoiesis: Effect of Growth Factors on the Colony Formation by Embryonic Cells"; Rich, Ivan, Experimental Hematology, Vol. 20, pp. 368-70 (1992)
FFF	"Specific Enhancement of Mouse CFU-E by Mouse Transferrin"; Rich, Ivan, et al, British Journal of Haematology, Vol. 49, pp. 567-573 (1981)
GGG	"The effect of reduced oxygen tension on colony formation of erythropoietic cells <i>in vitro</i> "; Rich, Ivan, & Kubanek, B., British Journal of Haematology, Vol. 52, pp. 579-588 (1982)
ННН	"Haemopoietic stem cells are organized for use on the basis of their generation-age"; Rosendaal, M., et al, Nature, Vol. 264, pp. 68-69 (1976)
III	"Circadian Variation in Cell Division of the Mouse Alimentary Tract, Bone Marrow and Corneal Epithelium"; Scheving, L., et al, Anat. Rec., Vol. 191, pp. 479-486 (1978)
111	"The Toxicology of Benzene"; Synder, Robert., et al, Environmental Health Perspectives, Vol. 100, pp. 293-306 (1993)
KKK	"What controls hair follicle cycling?"; Stenn, K.S., et al, Experimental Dermatology, Vol. 8, pp. 229-236 (1999)
LLL	"Distinct circadian time structures characterize myeloid and erythroid progenitor and multipotential cell clonogenicity as well as marrow precursor proliferation dynamics"; Wood, Patricia, et al, Experimental Hematology, Vol 26, pp. 523-533 (1998)

Sheet 5 of 5

MMM	"Expression of the Circadian Clock Genes <i>clock</i> and <i>period1</i> in Human Skin"; Zanello, Susana, et al, Journal of Invest Dermatol., Vol. 115, pp. 757-760 (2000)
NNN	"The sensitivity of in vitro erythropoietic progenitor cells to different erythropoietin reagents during development and the role of cell death in culture"; Zimmerman, Frank & Rich, Ivan, Experimental Hematology, Vol. 24, pp. 330-39 (1996)